

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
WESTERN DIVISION**

STEPHANIE KNOTH

PLAINTIFF

VS.

CAUSE ACTION NO.: 5:18-CV-49-DCB-MTP

DR. STEPHEN P. KEITH, ET AL.

DEFENDANTS

Order

This matter is before the Court on Apollo Endosurgery US, Inc., ("Apollo")'s Motion in Limine to Exclude Plaintiff's Medical Device Report. [ECF No. 165]. Having read the Motion, the submissions of the parties, applicable statutory and case law, the record, and being otherwise fully informed of the premises, the Court denies Apollo's Motion in Limine.

Background

This case is a medical malpractice and products liability dispute, arising from the implant of an ORBERA® gastric balloon manufactured by Apollo. Dr. Stephen Keith implanted the ORBERA® balloon in Ms. Knoth ("Plaintiff"). The Plaintiff experienced complications which ultimately led to the removal of the ORBERA®.

Apollo has filed a Motion in Limine to exclude Plaintiff's Medical Device Report. [ECF No. 165].

Discussion

It is unclear to the Court which document Apollo seeks to exclude. There are two documents: an internal complaint form [ECF No. 145]; and a Form 3500A Medical Device Report ("MDR") that Apollo submitted to the Food and Drug Administration ("FDA") [ECF No. 136-6]. The Court will assume that Apollo seeks to exclude both documents and will address each.

A. Internal Complaint Form [ECF No. 145]

The internal complaint form was the result of an internal investigation by Apollo. This document does not qualify as an MDR under 21 U.S.C. § 360i(a)(1) and (b)(1). It is strictly an internal form prepared by Apollo, which was not submitted to the FDA. It is not inadmissible under 21 U.S.C. § 360i(b)(3) because it was not made by: (A) a device user facility (i.e., the hospital), (B) an individual employed by or affiliated with such a facility, or (C) a physician not required to make such a report. See 21 U.S.C. § 360i(b)(3). The document was prepared by Apollo, the manufacturer. Apollo argues that because the information contained in its internal complaint form was used to prepare the Form 3500A MDR, which it ultimately submitted to the FDA, the internal complaint form (like an MDR described in Section 360i(b)(3)) should

not be admitted into evidence. The Court finds that there is no basis in the statute for this argument.

B. The MDR [ECF No. 136-6]

Apollo submitted a Form 3500A MDR to the FDA. Although this document is an "MDR", it is not the type that is inadmissible under Section 360i(b)(3) because, as noted above, it was not made by: (A) a device user facility (i.e., the hospital), (B) an individual employed by or affiliated with such a facility, or (C) a physician not required to make such a report. See 21 U.S.C. § 360i(b)(3). In its Form 3500A MDR, Apollo listed Dr. Keith as the "Initial Reporter", [ECF No. 136-6 at 1], and it argues that Form 3500A MDR is therefore inadmissible because it is based on information reported by Dr. Keith, who is an individual employed by or affiliated with a device user facility and a physician not required to make an MDR. The Court finds that this argument is not supported by the plain language of the statute. In addition, the Form 3500A MDR indicates that a "Company Representative" also was a source of the report. [ECF No. 136-6 at 2]. It implausible for Apollo to argue that Dr. Keith is responsible for its Form 3500A MDR, while the MDR itself attributes a "Company Representative" and a "Health Professional" as report sources. [ECF No. 136-6 at 2].

C. Federal Rule of Evidence 403

Apollo argues, in the alternative, that F.R.E. 403 provides grounds for excluding "Plaintiff's MDR." [ECF No. 166 at 4-6].

Apollo's Memorandum is unclear as to which document(s) it seeks to exclude under its alternative Rule 403 argument. Apollo's Memorandum only refers to excluding "Plaintiff's MDR" but does not provide a cite to a docket number. Plaintiff's Response in Opposition [ECF No. 173 at 4] assumes that Apollo solely seeks to exclude its internal complaint form under Rule 403. The Court finds that the probative value of neither document [ECF Nos. 136-6 & 145] is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence. See F.R.E. 403.

Conclusion

Neither the internal complaint form [ECF No. 145] nor the Form 3500A MDR [ECF No. 136-6] is inadmissible document under 21 U.S.C. § 360i(b)(3). As stated above, the Court finds that the probative value of these documents is not substantially outweighed by a danger of unfair prejudice, confusing issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.

Accordingly,

IT IS HEREBY ORDERED that Apollo's Motion in Limine to Exclude Plaintiff's MDR [ECF No. 165] is DENIED.

SO ORDERED, this the 1st day of February, 2021.

/s/ David Bramlette
UNITED STATES DISTRICT JUDGE